



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,454	01/24/2002	David Cooke	1627D	3228

7590

08/15/2003

Karen G. Kaiser
Intellectual Property
NATIONAL STARCH AND CHEMICAL COMPANY
10 Finderne Avenue
Bridgewater, NJ 08807-0500

EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 08/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary

Application No.

10/056,454

Applicant(s)

COOKE ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-37, 42-51, 53-63, 67, 68 and 73 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 27-37, 42-51, 53-63, 67, 68 and 73 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/945,722.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.5 6) ☐ Other: _____

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1638.

Applicant's election without traverse of Group I in Paper No. 9 is acknowledged.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specifically, the first paragraph of the specification, as added by the preliminary amendment of 24 January 2002, should be replaced with the following:

--This application is a divisional of application Serial No. 08/945,722 filed 18 December 1997, which is a 371 of PCT/GB96/01075 filed 3 May 1996.--

The specification is objected to on page 21 in its recitation of "Table 1 to be inserted here". No Table 1 could be found anywhere in the application file. Any reference to Table 1 in the specification should be deleted. The data intended for Table 1 may be presented in the form of a declaration under 37 CFR 1.132, which will be made part of the application file, but which will not be printed, should the application issue as a patent.

Claim 33 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim, i.e. claim 29. See MPEP § 608.01(n). In the interest of compact prosecution, the claim has been treated on the merits. Such treatment does not relieve Applicants of the responsibility to respond to this objection.

Claims 28-32 and 34 are objected to under 37 CFR 1.821(d) for their omission of Sequence Identifiers.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 27-34, 49 and 73 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 27-34 and 73 are drawn to nucleic acid molecules which are indistinguishable from naturally-occurring nucleic acid molecules, since they are not isolated. Claim 49 is drawn to progeny of a transformed plant, wherein the progeny may not retain the transgene, due to meiotic segregation, and so be indistinguishable from naturally occurring plants.

The DNA molecule and progeny, as claimed, have the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Amendment of claim 27, line 1 to replace "A" with --An isolated--; and amendment of claim 49 to specify that the progeny retains the introduced nucleotide sequence and the altered characteristics; would obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-37, 42-51, 53-63, 67-68 and 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any nucleotide sequence which encodes an "effective portion" of any length and sequence of a potato class A starch branching enzyme, "substantially" comprising particular nucleotide sequences or "substantially" encoding particular amino acid sequences, or "functional equivalents" thereof; methods for their use to transform plants, and the resultant transformed plants. In contrast, the specification only demonstrates the isolation and characterization of a full-length, native potato class A starch branching gene encoding SEQ ID NO:15, and plant transformation with a fragment of the native gene of at least 1200 contiguous base pairs which is inserted into the plant in antisense orientation with respect to a promoter. No guidance is provided for a multitude of sequence variants or portions of any length, or sequences

which comprise a portion of as little as one nucleotide base pair from the native potato class A branching enzyme gene and which further comprise a multitude of unspecified nucleotide base pairs.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of

sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Claims 27-37, 42-51, 53-63, 67-68 and 73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to nucleotide sequences encoding the full-length native potato class A starch branching enzyme of SEQ ID NO:15, and plant transformation with a fragment thereof of at least 1200 contiguous base pairs for the alteration of starch produced by the plant, does not reasonably provide enablement for claims broadly drawn to any sequence of any length encoding an "effective portion" of the enzyme, any sequence variant which

"substantially" encodes the native enzyme or a "functional equivalent" thereto; any method of altering the properties of starch produced by plants transformed with said sequence portions or variants or equivalents; or any method of altering any plant characteristic besides starch production following transformation with the native or modified gene sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to any nucleotide sequence which encodes an "effective portion" of any length and sequence of a potato class A starch branching enzyme, "substantially" comprising particular nucleotide sequences or "substantially" encoding particular amino acid sequences, or "functional equivalents" thereof; methods for their use to transform plants for altered starch production or alteration of any other plant characteristic, and the resultant transformed plants. In contrast, the specification only demonstrates the isolation and characterization of a full-length, native potato class A starch branching gene encoding SEQ ID NO:15, and plant transformation with a fragment of the native gene of at least 1200 contiguous base pairs which is inserted into the plant in antisense orientation with respect to a promoter, wherein said plant transformation results in altered properties of starch produced by the transformed plant. No guidance is provided for a multitude of sequence variants or portions of any length, or sequences which comprise a portion of as little as one nucleotide base pair from the native potato class A branching enzyme gene and which further comprise a multitude of unspecified nucleotide base pairs. Furthermore, no guidance is provided for altering

any other plant characteristic such as disease resistance, flowering time, drought resistance, etc.

The process of modifying starch accumulation in transgenic plants is particularly unpredictable. See Kossmann et al (1995), who teach the lack of influence of antisense potato starch accumulation genes on branching or phosphate content of starch (page 275, third through fifth full paragraphs), the difficulty inherent in isolating individual starch synthesis enzymes or their corresponding genes (paragraph bridging pages 275 and 276), and the lack of correlation between reduction of branching enzyme gene activity and branching of starch in transgenic plants (see, e.g., page 277, penultimate paragraph). See also Willmitzer et al (1993), who teach that plant transformation with an antisense branching enzyme gene construct failed to alter any property of starch produced by the plants (see, e.g., page 38, third full paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of sequence portions of any length or variants of any sequence of the native potato class A enzyme gene, or any of a multitude of sequences from any source which encode a multitude of "functional equivalents" thereof, and to evaluate the ability of the exemplified or non-exemplified sequences to alter starch production or any other trait of plants transformed therewith.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-29 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-29 are indefinite in their recitation of "sequence" in line 2, second occurrence, as it is unclear whether an amino acid or nucleotide sequence is intended, since Figure 5 presents both types. The following amendments would obviate this rejection:

In claim 28, line 2, insert --amino acid-- before "sequence", second recitation.

In claim 29, line 2, insert --nucleotide-- before "sequence", second recitation.

Claim 50 is indefinite for employing improper Markush terminology. Replacement of "one of the following" with --the group consisting of-- would obviate this rejection. See MPEP 2173.05(h).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-37, 42-51, 53-63, 67-68 and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by Willmitzer et al (U.S. 6,215,042 issued 10 April 2001, effectively filed 13 August 1993).

The claims are broadly drawn to a nucleotide sequence encoding an "effective portion" of a potato class A starch branching enzyme, a nucleotide sequence "substantially" encoding the enzyme, a nucleotide sequence which "substantially" comprises a sequence which encodes an enzyme, a nucleotide sequence which encodes a "functional equivalent" of the enzyme, and methods for plant transformation to produce plants which produce altered starch. The claims are also drawn to plant transformation with a construct which further comprises a second sequence which may comprise any portion of any length of a potato starch class B branching enzyme, optionally in antisense orientation with respect to a second promoter.

Willmitzer et al teach an isolated starch branching enzyme gene from potato, which "substantially" encodes SEQ ID NO:15 or an effective portion thereof, and which is "substantially" SEQ ID NO:14 or SEQ ID NO:18; vectors comprising the starch branching enzyme gene in sense or antisense orientation with respect to a promoter, and also teach potato plants transformed therewith; wherein said plants produce starch having altered properties; wherein the vector comprising the potato branching enzyme gene comprises a second selectable marker gene which would inherently additionally comprise at least one nucleotide base pair of a class B starch branching enzyme gene in antisense orientation with respect to a promoter (see, e.g., Sequence Search results appended to the patent, and also see Figures 1-2 and columns 7-8, columns 11-14).

The claimed starch properties would have been inherent in the altered starch produced by the potato plants of Willmitzer et al.

Claims 27-37, 42-51, 53-63, 67-68 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/14827 (INSTITUT FUR GENBIOLOGISCHE).

INSTITUT (1993) is the PCT parent of Willmitzer et al (U.S. 6,215,042) and thus teaches the same concepts as the U.S. patent (see entire document).

Claims 27-37, 42-51, 53-63, 67-68 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/07355 (INSTITUT FUR GENBIOLOGISCHE).

INSTITUT (1995) teach potato plant transformation with a gene construct comprising a potato starch branching enzyme gene in antisense orientation with respect to a promoter, said construct further comprising a disproportionation enzyme gene in antisense orientation with respect to a promoter, wherein said potato starch branching enzyme gene is the same as that taught by INSTITUT (1993), and wherein the disproportionation enzyme gene would comprise at least one base pair of a potato class B starch branching enzyme; and also teach potato plants transformed therewith, wherein the potato plants produce starch with altered branching and phosphate contents (see, e.g., page 3, lines 19-25; page 5, line 23 through page 6, line 22; pages 7-8; pages 14-16; pages 19-20; Figures 1-5). The claimed starch properties would have been inherent to the starch with altered branching and phosphate content taught by the reference.

No claim is allowed.

Art Unit: 1638

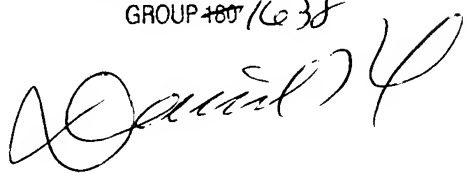
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 11, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the printed name and title. The signature is stylized with a large, looping initial "D".